



United States Attorney
Southern District of New York

86 Chambers Street
New York, New York 10007

February 27, 2015

BY ECF

Honorable James C. Francis
United States Magistrate Judge
U.S. Courthouse, 500 Pearl Street
New York, NY 10007

Re: *United States ex rel. Kester v. Novartis Pharmaceuticals, Corp.*, 11 Civ. 8196 (CM) (JCF)

Dear Judge Francis:

On behalf of plaintiffs the United States (the “Government”) and the eleven States that intervened in this action (collectively, the “Litigating States”), we respectfully submit this letter to seek a conference with the Court regarding a discovery issue. Briefly, defendant Novartis announced on February 17 that, because it “plan[s] to emphasize that plaintiffs cannot prove the requisite intent to violate the AKS,” it had decided to waive privilege in relation to Exjade and will proffer testimony from two lawyers. This announcement came nearly seven months after Novartis indicated it did not intend to assert a reliance on the advice of counsel defense in response to a July 2014 inquiry from the Government on that subject.¹

Because Novartis’s waiver announcement came just two months before the close of fact discovery on April 17, the Government and the Litigating States sought prompt production of documents subject to waiver. Novartis initially stated it did not “anticipate that the volume of these documents will be significant.” This week, however, Novartis indicated it does not foresee completing production until “mid-March.” Further, other than various attorneys, Novartis has failed to identify the witnesses who purportedly sought, received, or implemented legal advice concerning Exjade.

Novartis’s belated decision to waive privilege, its delay in producing documents, and its failure to identify the individuals who purportedly sought, received, and implemented legal advice are preventing the Government and the Litigating States from deposing the Exjade witnesses at Novartis.² First, until we receive documents showing what Novartis told counsel in seeking legal advice, what counsel advised Novartis it was and was not permitted to do, and what

¹ A copy of this email exchange is attached.

² Indeed, Novartis already has forced the Government and the Litigating States to adjourn previously scheduled depositions of Novartis’s Exjade witnesses due to late productions of hundreds of thousands of pages of documents. On February 11, Novartis advised us, one day before the scheduled deposition of one of Novartis’s Exjade witnesses, that it had overlooked documents relevant to that witness and two other witnesses scheduled to be deposed in February. Those late-produced documents, which totaled over 585,000 pages, required the Government and the Litigating States to adjourn these three depositions. Further, we currently are waiting for Novartis to finish producing 65,000 documents – apart from the documents subject to the waiver – that bear on the depositions of Novartis’s Exjade witnesses. Finally, even now, Novartis has not agreed to state when it intends to finish producing the documents that it plans to rely on at trial.

steps Novartis took to implement such advice, we cannot effectively depose the Exjade witnesses whose depositions we have already have noticed. Indeed, the ten documents Novartis unredacted in response to relator's pending motion to compel show that three of the Novartis witnesses previously scheduled to be deposed in February – Kenneth Olsen, Peter Ng, and Emily Chee – discussed Exjade-related legal advice (including the significance of legal advice Novartis received previously concerning incentives for pharmacies for other drugs). Without a full document production, we do not know whether those or other witnesses withheld information relevant to counsel's assessment of Exjade activities, we cannot determine whether those or other witnesses were given legal advice relevant to their Exjade-related job duties and we cannot assess whether those or other witnesses followed any legal advice they were given. Further, until Novartis identifies the witnesses involved with seeking, giving, and implementing legal advice, the Government and the Litigating States have no assurance that we have noticed all the appropriate witnesses for depositions. Finally, it is unclear how Novartis is collecting the documents relevant to any legal advice concerning Exjade, what documents it plans to withhold based on a purported legal advice/work-product distinction, or whether it is collecting documents not only from within Novartis, but also from law firms giving legal advice concerning Exjade.

Under these circumstances, we are concerned that – unless Novartis is ordered to finish its production promptly, to take steps to ensure that its production is comprehensive, and to answer the Government's questions – the Government and the Litigating States will face insurmountable hurdles to comply with the discovery cut-offs that the Court set on September 19, 2014. Accordingly, we respectfully seek a conference with the Court so that we can ask the Court to direct Novartis to (i) take steps to ensure that its production of the "waiver" documents contain all documents relevant to legal advice that bears on any aspect of Novartis's relationship with the three Exjade pharmacies, regardless of whether it specifically references Exjade or adherence; (ii) finish producing those documents by March 4, and (iii) separately identify all witnesses involved with requesting, receiving, providing, and implementing legal advice concerning Exjade by March 4. If Novartis fails to comply with these deadlines, we will be compelled to seek an extension to the discovery deadlines in this case or other appropriate remedy (at present, fact discovery is scheduled to close on April 17, and expert discovery is scheduled to close on May 29, 2015).

We thank the Court for its consideration of this letter and the request for a conference.

Respectfully,

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